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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/733,338	12/08/2000	Karla Ann Joyce	13148.1USU1	2271

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EXAMINER	
NAJARIAN, LENA	
ART UNIT	PAPER NUMBER
3626	

DATE MAILED: 01/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/733,338	JOYCE ET AL.	
	Examiner	Art Unit	
	Lena Najarian	3626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 December 2000*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *11 June 2001* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Drawings

1. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: item 94 in Figure 5. Corrected drawing sheets, or amendment to the specification to add the reference character(s) in the description, are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. Claims 1-15 recite the limitations for which there is no antecedent basis in the claims. In particular, the following passages lack or have vague antecedent basis:

(i) "the patient's": claim 1, lines 3-4

(ii) "the index number": claim 9, line 2

(iii) "the objective findings": claim 10, lines 2-3 & claim 11, lines 2-3

(iv) "the level of subjective complaints": claim 10, line 3 & claim 11, line 3

(v) "the diagnosis": claim 12, line 2 & claim 13, line 2

(vi) "the medical record": claim 12, line 3 & claim 13, line 3.

(vii) Claims 2-15 incorporate the deficiencies of claim 1, through dependency, and are also rejected.

Claim Rejections - 35 USC § 101

5. Claims 1-15 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

The basis of this rejection is set forth in a two-prong test of:

(1) whether the invention is within the technological arts; and

(2) whether the invention produces a useful, concrete, and tangible result.

For a claimed invention to be statutory, the claimed invention must be within the technological arts. Mere ideas in the abstract (i.e., abstract idea, law of nature, natural phenomena) that do not apply, involve, use, or advance the technological arts fail to promote the "progress of science and the useful arts" (i.e., the physical sciences as opposed to social sciences, for example) and therefore are found to be non-statutory

subject matter. For a process claim to pass muster, the recited process must somehow apply, involve, use, or advance the technological arts.

In the present case, claims 1-15 only recite an abstract idea. The recited steps of exemplary claim 1 of merely reviewing patient care and assessing time-dependent treatment protocols does not apply, involve, use, or advance the technological arts since all of the recited steps can be performed in the mind of the user or by use of a pencil and paper.

Additionally, for a claimed invention to be statutory, the claimed invention must produce a useful, concrete, and tangible result. In the present case, the claimed invention combines subjective and objective data of a patient's medical condition to generate a treatment index and to determine appropriate treatment frequency. Although the recited process produces a useful, concrete, and tangible result, since the claimed invention, as a whole, is not within the technological arts as explained above, claims 1-15 are deemed to be directed to non-statutory subject matter.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 1-6 and 10-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bond et al. (6,177,940) in view of Martin et al. (US 2002/0004725 A1).

(A) Referring to claim 1, Bond discloses a method of reviewing patient care and assessing time-dependent treatment protocols, the method comprising (col. 2, lines 39-45 of Bond):

a) determining subjective data of the patient's medical condition (col. 3, lines 31-38 of Bond);

b) determining objective data of the patient's medical condition (col. 2, lines 39-45 of Bond; the Examiner interprets "the responsiveness of a particular patient to a therapy" and "recovery rate" to be forms of objective data); and

c) combining the subjective and objective data to generate a treatment index (col. 18, lines 1-11 of Bond; the Examiner interprets "scores" to be a form of treatment index).

Bond does not disclose d) using the treatment index to determine appropriate treatment frequency.

Martin discloses using the treatment index to determine appropriate treatment frequency (para. 28, lines 4-7 of Martin; the Examiner interprets "a treatment planning model" that "requires fewer procedures" to be a form of treatment frequency).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the feature of Martin within Bond. The motivation for doing so would have been to yield higher quality and more effective healthcare (para. 28, lines 6-7 of Martin).

(B) Referring to claim 2, Bond discloses wherein the step of determining subjective data comprises review of the severity and frequency of injury symptoms (col. 3, lines 34-38,

Fig. 9B, item 936, and Fig. 11C of Bond; the Examiner interprets "pain during daily activity" to be a measure of the frequency of symptoms).

(C) Referring to claim 3, Bond discloses wherein the step of determining subjective data further includes correction for redundant symptoms (col. 1, lines 22-28 of Bond; the Examiner interprets "treatment plan" to be a form of "correction for redundant symptoms").

(D) Referring to claim 4, Bond discloses wherein the step of determining subjective data comprises review of the severity and frequency of injury includes correction for redundant symptoms (col. 1, lines 22-28 of Bond; the Examiner interprets "treatment plan" to be a form of "correction for redundant symptoms").

(E) Referring to claim 5, Bond discloses wherein the step of determining objective data comprises review of test results (col. 18, lines 8-11 of Bond; the Examiner interprets "assessment of the effectiveness" to be essentially a type of "review of test results").

(F) Referring to claim 6, Bond discloses wherein the step of determining objective data comprises combining a plurality of tests to obtain a composite objective data score (col. 18, lines 8-11 of Bond).

(G) Referring to claim 10, Bond does not disclose wherein the step of combining the subjective and objective data to form an index comprises determination of whether or not the objective findings support the level of subjective complaints.

Martin discloses determination of whether or not the objective findings support the level of subjective complaints (para. 5 of Martin).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the feature of Martin within Bond. The motivation for doing so would have been for the healthcare provider to form hypotheses about the cause of the condition, its severity, and its impact (para. 5, lines 1-3 of Martin).

(H) Referring to claim 11, Bond does not disclose wherein the step of combining the subjective and objective data to form an index comprises determination of whether or not the objective findings are disproportionately high compared to the level of subjective complaints.

Martin discloses determination of whether or not the objective findings are disproportionately high compared to the level of subjective complaints (para. 6 of Martin; the Examiner interprets "quantified measure" to be a form of "level").

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the feature of Martin within Bond. The motivation for doing so would have been to use the findings to diagnose a condition or disease (para. 6, lines 6-7 of Martin).

(I) Referring to claim 12, Bond does not disclose wherein the step of combining the subjective and objective data to form an index comprises identification of whether the diagnosis is linked to a part of the body for which there are no subjective complaints in the medical record.

Martin discloses using a risk assessment tool to identify whether the diagnosis is linked to a part of the body for which there are no subjective complaints in the medical record (para. 34 of Martin).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the feature of Martin within Bond. The motivation for doing so would have been to predict an appropriate treatment plan based on clinical data and data reflecting the patient's behavior (para. 34, lines 5-10 of Martin).

(J) Referring to claim 13, Bond does not disclose wherein the step of combining the subjective and objective data to form an index comprises identification of whether the diagnosis is linked to a part of the body for which there are no objective findings listed in the medical record.

Martin discloses identification of whether the diagnosis is linked to a part of the body for which there are no objective findings listed in the medical record (para. 34 of Martin).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the feature of Martin within Bond. The motivation for doing so would have been to predict an appropriate treatment plan (para. 34, lines 5-10 of Martin).

(K) Referring to claim 14, Bond discloses a patient examination (col. 18, lines 49-53 of Bond; the Examiner interprets "clinic visit" to be a form of patient examination).

(L) Referring to claim 15, Bond discloses preparing a report (Fig. 8B and col. 10, lines 16-19 of Bond).

8. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bond et al. (6,177,940) in view of Martin et al. (US 2002/0004725 A1) as applied to claims 1 and 6 above, and further in view of Coli et al. (6,018,713).

(A) Referring to claim 7, Bond and Martin do not disclose wherein the step of determining objective data comprises eliminating similar tests.

Coli discloses eliminating similar tests (col. 19, lines 60-67 of Coli).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the feature of Coli within Bond and Martin. The motivation for doing so would have been for a complete and accurate test selection (col. 19, lines 64-67 of Coli).

9. Claims 8-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bond et al. (6,177,940) in view of Martin et al. (US 2002/0004725 A1) as applied to claims 1 and 6 above, and further in view of Cohen (4,346,697).

(A) Referring to claim 8, Bond and Martin do not disclose wherein the step of combining the subjective and objective data to form an index comprises identification of cases in which the number of subjective complaints has increased from the previous examination.

Cohen discloses identification of cases in which the number of subjective complaints has increased from the previous examination (col. 2, lines 11-21 of Cohen; the Examiner interprets "the patient feeling worse" to produce an increase in the number of subjective complaints).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the feature of Cohen within Bond and Martin. The motivation for doing so would have been for the doctor to determine whether the patient is responding to the medication (col. 2, lies 35-36 of Cohen).

(B) Referring to claim 9, Bond and Martin do not disclose wherein the step of combining the subjective and objective data to form an index comprises determination of whether the index number has increased since the previous examination, or the number of subjective complaints has increased from the previous exam data.

Cohen discloses the determination of whether the index number has increased since the previous examination or the number of subjective complaints has increased from the previous exam data (col. 1, lines 44-51 and col. 2, lines 11-21 of Cohen; the Examiner interprets "a graph of the patient's reaction" to be a form of determining whether the index number has increased).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the feature of Cohen within Bond and Martin. The motivation for doing so would have been for the patient to be able to actively participate in his treatment and in return, improve patient progress (col. 1, lines 46-51 of Cohen).

Conclusion

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The cited but not applied prior art teaches a computerized

medical diagnostic system including re-enter function and sensitivity factors (5,594,638) and a health care data manipulation and analysis system (US 6,230,142 B1).

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lena Najarian whose telephone number is (703) 305-0260. The examiner can normally be reached on Monday - Friday, 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached on (703) 305-9588. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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12-8-04

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